Application/Control Number: 10/535,013 Art Unit: 1657

DETAILED ACTION

The IDS received 9/6/2005, the preliminary amendment received 5/12/2005 have been entered

Claims 17-31 are presented for examination on the merits.

Claim Objections

Claims 30-31 are objected to because of the following informalities: the word "to" is missing after "according" on line 1 in each occurrence. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 17-21, 27-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Nothwehr et al. (1989).

Nothwehr et al. teach a (screening) method for determining the significance of a plurality of variants (read as wild type and at least one mutant variants) of at least one gene comprising:
(a) obtaining a sample of at least one protein variant (read as mutant AIV Δ 14, see page 4645, Fig. 4) encoded by the plurality of variants of said at least one gene; (b) exposing the protein encoded by said nucleic acid molecule to a plurality of proteases (page 4645, Fig. 4, legend); (c) determining an extent of proteolytic cleavage of said protein (page 4645, Fig. 4); and, optionally,(d) comparing said extent of proteolytic cleavage of the protein encoded by said nucleic acid molecule with an extent of proteolytic cleavage of a wild-type protein when exposed to said plurality of proteases (page 4645, Fig. 4); wherein said at least one protein variant is exposed to a plurality of protease (trypsin and chymotrypsin, page 4645, Fig. 4 legend) that attach different sites within the at least one protein variant; wherein said extend of proteolytic cleavage is determined using a conventional protein SDS-PAGE analysis with blotting (page

4645, Fig. 4); wherein additional studies are undertaken to determine the functionality of the at least one protein variant (page 4646, left column, 1st full paragraph, also see abstract).

Claims 18, 22-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Kardos et al. (1999).

Kardos et al. teach a (screening) method for determining the significance of a plurality of variants (read as wild type and mutants, see abstract, lines 6-7) comprising: (a) obtaining a sample of at least one protein variant (read as variants of mutants, page 12252, left column, 1st full paragraph, lines 25-31) encoded by the plurality of variants of said at least one gene; (b) exposing the protein to at least one proteases: pepsin (page 12250, right column, 6th full paragraph); (c) determining an extent of proteolytic cleavage of said protein (page 12251, left column, lines 1-4); and, optionally,(d) comparing said extent of proteolytic cleavage of the protein with an extent of proteolytic cleavage of a wild-type protein when exposed to proteases (page 12254, left column, 2nd full paragraph, and Fig. 7); wherein said extend of proteolytic cleavage is determined using a conventional protein SDS-PAGE analysis with blotting (page 12251, left column, lines 1-4); wherein additional studies are undertaken to determine the functionality of the at least one protein variant (page 12254, left column, 2nd full paragraph, and also DISCUSSION on page 12254).

Claims 17-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Chiang et al. (2001).

Chiang et al. teach a (screening) method for determining the significance of a plurality of variants (read as wild type GFP and its mutant variants, see Abstract) of at least one gene comprising: (a) obtaining a sample of at least one protein variant or plurality of protein variants (page 230, left column, 2nd and 3rd full paragraph) encoded by the plurality of variants of said at least one gene; (b) exposing the protein encoded by said nucleic acid molecule to a plurality of proteases (page 230, right column, 3rd full paragraph, and also page 232, Fig. 2 and page 233, Table II); (c) determining an extent of proteolytic cleavage of said protein (page 232, Fig. 2 and page 233, Table II); and, optionally, (d) comparing said extent of proteolytic cleavage of the protein encoded by said nucleic acid molecule with an extent of proteolytic cleavage of a wild-

Application/Control Number: 10/535,013 Art Unit: 1657

type protein when exposed to said plurality of proteases (page 232, Fig. 2 and page 233, Table II); wherein said at least one protein variant is exposed to a plurality of protease (trypsin/pronase/proteinase K, page 232, left column, lines 2-3, also see page 232, Fig. 2 and page 233, Table II) that attach different sites within the at least one protein variant; wherein said extend of proteolytic cleavage is determined using a conventional protein SDS-PAGE analysis with blotting (page 230, right column, 3rd full paragraph, also see page 232, Fig. 2); wherein additional studies (read as fluorescence measurement, see page 232, end of right column) are undertaken to determine the functionality of the at least one protein variant (page 233, Fig. 3).

Therefore, the cited reference is deemed to anticipate the instant claims above.

Conclusion

No claim is allowed.

Certain papers related to this application may be submitted to Art Unit 1657 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone number for the Group is 571-273-8300. NOTE: If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the

problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning rejections or objections in this communication or earlier communications from the examiner should be directed to Bin Shen, Ph.D., whose telephone number is (571) 272-9040. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (i.e., shortly after the examiner returns to her office).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor. Dr. Jon Weber can be reached at (571) 272-0925.

B.Shen

Art Unit 1657

/JON P WEBER/

Supervisory Patent Examiner, Art Unit 1657